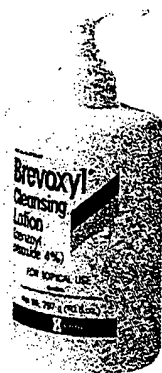


Kills *P. acnes*...
With Kindness

Brevoxyl[®] Cleansing Lotion (benzoyl peroxide 4%)



For Topical Use

INDICATIONS AND USAGE: Brevoxyl Cleansing Lotion is indicated for use in the topical treatment of mild to moderate acne vulgaris. Brevoxyl Cleansing Lotion may be used as an adjunct in acne treatment regimens including antibiotics, retinoic acid products, and sulfur/salicylic acid containing preparations.

CONTRAINDICATIONS: Brevoxyl Cleansing Lotion should not be used in patients who have known hypersensitivity to benzoyl peroxide or to any of the other ingredients in the product.

PRECAUTIONS: General - For external use only. Avoid contact with eyes and mucous membranes. AVOID CONTACT WITH HAIR, FABRICS OR CARPETING AS BENZOYL PEROXIDE WILL CAUSE BLEACHING.

Carcinogenesis, Mutagenesis, Impairment of Fertility - Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice born to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

Pregnancy: Category C - Animal reproduction studies have not been conducted with benzoyl peroxide. It is also not known whether benzoyl peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl peroxide should be used by a pregnant woman only if clearly needed.

Nursing Mothers - It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman.

Pediatric Use - Safety and effectiveness in children below the age of 12 have not been established.

ADVERSE REACTIONS: Contact sensitization reactions are associated with the use of topical benzoyl peroxide products and may be expected to occur in 10 to 25 of 1,000 patients. The most frequent adverse reactions associated with benzoyl peroxide use are excessive erythema and peeling which may be expected to occur in 5 of 100 patients. Excessive erythema and peeling most frequently appear during the initial phase of drug use and may normally be controlled by reducing frequency of use.

HOW SUPPLIED: Brevoxyl Cleansing Lotion is supplied in 297 g (10.5 oz.) plastic bottles. NDC 0145-2310-05. Store at controlled room temperature 15°-30°C (59°-86°F).

CAUTION: Federal law prohibits dispensing without a prescription.

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Diaper Dermatitis: An Approach to Prevention Employing Effective Diaper Care

Camila K. Janniger, MD
Isabelle Thomas, MD

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Diaper dermatitis is a ubiquitous problem in infants wearing diapers (Figure 1) and is becoming an increasingly important part of elderly care. Estimates of its prevalence vary from 4 to 15 percent between the ages of birth to two years, but this is probably a gross underestimation of the problem as most cases are not brought to a physician's attention.¹ Diaper dermatitis is generally caused by a primary irritant dermatitis and is the result of a number of factors.²⁻⁵ Secondary infection with *Candida* or bacteria may be involved. Individual predispositions play a role, particularly in infants with underlying atopic or seborrheic dermatitis. In rare cases, histiocytosis X, nutritional deficiencies such as zinc deficiency (acrodermatitis enteropathica), and inborn errors of metabolism such as multiple carboxylase deficiency or maple syrup urine disease⁶ may have to be considered if the rash does not respond to treatment.

Clinical Description

Diaper dermatitis usually affects the skin in closest contact to the diaper and involves the buttocks, upper thighs, lower abdomen, and genitalia. It consists of shiny erythematous patches at first, often with a papular or vesicular component. Fissures and erosions are often evident in the folds because of maceration. Often after two to three days, secondary infection with *Candida* occurs and characteristic satellite pustules may be observed. Rarely, a few red to purplish nodules may be mixed with the diaper dermatitis, as seen in granuloma gluteale infantum.⁷ The cause of the reaction is unclear, but the use of fluorinated topical steroids and occlusion have been blamed. The condition usually resolves spontaneously.

Diagnosis

The diagnosis of diaper dermatitis is often clear, but other dermatoses may trigger or mimic the eruption (Table I). Atopic dermatitis has similar sites of predilection: scalp, face, diaper areas, and extensor limb surfaces. Diaper dermatitis may represent a flexural form of seborrheic dermatitis; widespread erythema may also be evident, often with a cheesy exudate. Autoeczematization may occur with diaper dermatitis, producing a generalized papular or papulovesi-

cular eruption. Axillary involvement favors seborrheic dermatitis, as does lack of pruritus and absence of oozing and weeping. The distinction is really a clinical one, as elevated IgE levels associated with atopic dermatitis are a nonspecific finding.⁴ Sometimes there seems to be a combined form of atopic dermatitis and seborrheic dermatitis, with cradle cap being evident. However, the mixed features may reflect a true mixture, as infants with seborrheic dermatitis may exhibit an increased incidence of atopy which is in between that of normal controls and atopic patients.⁸

Another rare generalized form of dermatitis that may involve the diaper area is a special type of infantile seborrheic dermatitis. It may be associated with a variety of immune deficiencies in children with diarrhea and failure to thrive.⁹ Whether one considers the latter form of generalized infantile seborrheic dermatitis under the same rubric as an epidemic eruption of infants reported as erythroderma desquamativum by Leiner from Vienna in 1908 (Leiner's disease) is a matter of opinion.¹⁰⁻¹¹ Nevertheless, infants with generalized seborrheic dermatitis, diarrhea, and failure to thrive should be evaluated for possible immune deficits, particularly for a functional defect in the fifth component of complement. In addition, other defects have been described.¹²⁻¹³

Rarely, infants are affected with a scaling seborrheic dermatitis-like eruption in association with fever and other systemic signs of Letterer-Siwe disease (acute histiocytosis X).¹⁴⁻¹⁵

Psoriasis vulgaris is uncommon in infancy but may involve the diaper and flexural areas. Other evidence of psoriasis such as psoriasiform lesions elsewhere on the body or pitting of the nails may also facilitate distinction.

Congenital syphilis with diaper region involvement consists of erythematous macules and papules that may take on a coppery coloration. Other stigmata of secondary syphilis may be evident.

Mothers are often concerned about diaper dermatitis reflecting a vitamin deficiency. Although it probably does not occur in any given patient, it is necessary for the physician to selectively evaluate children for zinc deficiency (acrodermatitis enteropathica), biotin deficiency, and other deficiency states producing a dermatitis.¹⁶⁻¹⁷

Etiology

Diaper dermatitis is the result of a combination of factors, including occlusion, maceration, and abrasion. Frequent bowel movements and diarrhea increase the frequency of an eruption. Prolonged wetness leads to maceration, great-

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Figure 1. Infant with diaper dermatitis.

er friction, increased skin permeability, and microbial growth. *Candida* can be cultured from the area in 40 per-

cent of cases seventy-two hours after the beginning of the eruption.¹⁸ *Staphylococcus aureus* is often involved with underlying atopic dermatitis.¹⁹ It was thought that urinary ammonia from ammonia-producing microorganisms induced diaper dermatitis. However, the free ammonia in infants with diaper dermatitis was found to be the same as in normal infants as was the incidence of ammonia-producing bacteria.²⁰ Bacteria probably contribute to increasing the pH level, which promotes fecal enzyme activity, in particular proteases and lipases that act as irritants.²¹ Breast-fed babies have a lower incidence of rashes because their urinary pH is more acidic.

Proper Diaper Care and Treatment

The best approach to diaper care is prevention. Ideally a diaper should keep the skin as dry as possible, limit mixing of feces and urine, and keep pH at a normal acidic level. Controversy persists over the choice of cloth and disposable diapers, but most authors agree that the latest disposable diapers which contain an absorbent gelling material within the cellulose core are associated with a reduced prevalence of rashes, even in atopic babies.²²⁻²⁴ These diapers are also more resistant to leaks and reduce the risk of transmission of enteric pathogens, particularly in day-care settings. Although both cloth and disposable diapers create detrimental effects to the environment, superabsorbent diapers offer significant health benefits.²⁵

TABLE I
CAUSES OF DIAPER DERMATITIS

Primary irritant dermatitis
Candidosis
Seborrheic dermatitis
Atopic dermatitis
Psoriasis
Allergic contact dermatitis
Congenital syphilis
Zinc deficiency
Biotin deficiency
Histiocytosis X

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The usual approach to diaper dermatitis is a gentle one that mandates proper diaper usage.² Frequent diaper changes are mandatory. The diaper area should be gently cleansed with lukewarm water and patted dry. Commercial wipes that contain irritants and soap should be avoided if there is a rash. Zinc oxide is cheap and very effective at protecting the skin. It is our first choice both for prevention and therapy in most cases. Cornstarch may be used sparingly to dry the area if vesicles or maceration are present, but respiratory difficulties have been reported when used in excessive amount and inhaled by the infant.²⁶⁻²⁷

When atopic or seborrheic dermatitis is associated, a nonfluorinated topical steroid such as 1 percent hydrocortisone may be useful. With secondary *Candida* infection, the use of topical antifungals such as clotrimazole is beneficial.

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